

NEUROLOGICAL DEVICES PANEL
of the
MEDICAL DEVICES ADVISORY COMMITTEE

Fifteenth Meeting

Holiday Inn
Walker and Whetstone Ballroom
2 Montgomery Village Avenue
Gaithersburg, Maryland
August 5, 2003

Panel Chairperson
Robert W. Hurst, M.D.

Executive Secretary
Janet L. Scudiero, M.S.

10:30	am	Call to Order Conflict of Interest and Deputization to Voting Member Status Statements Panel Introductions Update Since the November Date, 2000 Meeting Stephen P. Rhodes, M.S., Chief, General and Plastic Surgery Devices Branch
10:45	am	Open Public Hearing* , up to 30 minutes
11:15	am	Microtherapeutics, Inc. Presentation on PMA 030004, The Onyx(r) Liquid Embolic System Amy Walters, VP Quality Assurance, Clinical & Regulatory Bill Patterson, Sr. Director, Research & Development Gary Duckwiler, MD, Principal Investigator Donald W. Larsen, MD, DSMB Lee Pride, MD, Clinical Investigator Tom Wilder, President/CEO
12:15	am	Lunch Break
1:00	am	FDA Presentation Peter L. Hudson, Ph.D., Preclinical Reviewer Ann Costello, Ph.D., M.D.M., Clinical Reviewer Judy Chen, M.S., Statistical Reviewer
1:45	pm	Panel Deliberations Thomas L. Kurt, M.D., M.P.H., Preclinical Review Mary Lee Jensen, M.D., Clinical Review Jonas Ellenburg, Ph.D., Statistical Review
3:15	pm	Break
3:30	pm	Second Open Public Hearing* , up to 30 minutes
4:00	pm	FDA and Sponsor Summations , up to 15 minutes each
4:30	pm	Concluding Deliberations and Vote
5:30	pm	Adjournment

* **Open Public Hearings** - Interested persons may present data, information, or views, orally or in writing, on the issue pending before the panel. Scheduled speakers who have requested time to address the panel will speak at this time. After they have spoken, Dr. Hurst may ask them to remain if the panel wishes to question them. Then Dr. Hurst will recognize unscheduled speakers as time allows.

Note: Only the panel may question speakers during the open public hearing